

# EXHIBIT 4

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COMPANY CONFORMED NAME:

ORGANOGENESIS INC

CENTRAL INDEX KEY:

0000779733

STANDARD INDUSTRIAL CLASSIFICATION:

BIOLOGICAL PRODUCTS (NO DIAG

IRS NUMBER:

042871690

STATE OF INCORPORATION:

DE

FISCAL YEAR END:

1231

FILING VALUES:

FORM TYPE: 10-Q

SEC ACT:

SEC FILE NUMBER: 001-09898

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BUSINESS ADDRESS:

STREET 1: 150 DAN RD

CITY: CANTON

STATE: MA

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BUSINESS PHONE: 6175750775

MAIL ADDRESS:

STREET 1: 150 DAN ROAD

STREET 2: 150 DAN ROAD

CITY: CANTON

STATE: MA

ZIP: 01002

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<TYPE>10-Q

<SEQUENCE>1

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UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION

Washington, D. C. 20549

## FORM 10-Q

[X] QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d)  
OF THE SECURITIES EXCHANGE ACT OF 1934

FOR THE QUARTERLY PERIOD ENDED MARCH 31, 2000

OR

[ ] TRANSITION REPORT PURSUANT TO SECTION 13 OR 15 (d)  
OF THE SECURITIES EXCHANGE ACT OF 1934

FOR THE TRANSITION PERIOD FROM \_\_\_\_\_ TO \_\_\_\_\_

COMMISSION FILE NUMBER 1-9898  
-----

ORGANOGENESIS INC.

(Exact name of registrant as specified in its charter)

DELAWARE  
-----

04-2871690  
-----

(State or other jurisdiction of  
incorporation or organization)

(I.R.S. Employer  
Identification number)

150 DAN ROAD, CANTON, MA  
-----

02021  
-----

(Address of principal executive offices)

(Zip Code)

Registrant's telephone number, including area code: (781) 575-0775  
\_\_\_\_\_

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes ( X ) No ( )

The number of shares outstanding of registrant's Common Stock, par value \$.01 per share, at May 3, 2000 was 34,032,864 shares (excluding treasury shares).  
<PAGE>

ORGANOGENESIS INC.

INDEX  
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PART I - FINANCIAL INFORMATION  
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PAGE  
NUMBER  
-----

## Item 1 - Financial Statements

Consolidated Balance Sheets at December 31, 1999 and March 31, 2000.....	3
Consolidated Statements of Operations for the three months ended March 31, 1999 and 2000..	4
Consolidated Statements of Cash Flows for the three months ended March 31, 1999 and 2000..	5
Notes to Consolidated Financial Statements.....	6

Item 2 - Management's Discussion and Analysis of Financial Condition and Results of Operations.....	10
--	----

## PART II - OTHER INFORMATION

- - - - -

Item 1 - Legal Proceedings.....	*
Item 2 - Changes in Securities.....	15
Item 3 - Defaults upon Senior Securities.....	*
Item 4 - Submission of Matters to a Vote of Security Holders..	*
Item 5 - Other Information.....	*
Item 6 - Exhibits and Reports on Form 8-K.....	15
Signatures.....	16

In this report, "Organogenesis" "we" "us" and "our" refer to Organogenesis Inc.

\* No information provided due to inapplicability of item

2

&lt;PAGE&gt;

## PART I - FINANCIAL INFORMATION

## Item 1 - Financial Statements

## ORGANOGENESIS INC.

Consolidated Balance Sheets  
(In thousands, except share data)

&lt;TABLE&gt;

&lt;CAPTION&gt;

December 31  
1999  
-----

&lt;S&gt;

&lt;C&gt;

## ASSETS

## Current assets:

Cash and cash equivalents	\$ 5,727
Investments	6,712
Inventory	906
Receivable from related party	985

Other current assets	643
	-----
Total current assets	14,973
Property and equipment -	
Less accumulated depreciation of \$11,080 and \$11,517	11,731
Other assets	601
	-----
Total Assets	\$ 27,305
	=====
Liabilities	
Current liabilities:	
Accounts payable	\$ 1,378
Accrued expenses	3,438
Advance from related party	-
Other current liabilities	996
Series C redeemable convertible preferred stock	6,180
	-----
Total current liabilities	11,992
Long-term convertible debt	17,953
Term loan	4,334
Commitments (see notes)	
Stockholders' Equity (Deficit)	
Common stock, par value \$.01; authorized 80,000,000 shares:	
issued 30,689,019 and 34,073,829 shares as of	
December 31, 1999 and March 31, 2000, respectively	307
Additional paid-in capital	122,890
Accumulated deficit	(129,367)
Treasury stock at cost, 85,000 shares at December 31, 1999	
and March 31, 2000	(804)
	-----
Total stockholders' equity (deficit)	(6,974)
	-----
Total Liabilities and Stockholders' Equity (Deficit)	\$ 27,305
	=====

&lt;/TABLE&gt;

The accompanying notes are an integral part of the consolidated financial statements.

&lt;PAGE&gt;

## ORGANOGENESIS INC.

Consolidated Statements of Operations  
(Unaudited, in thousands, except share data)

&lt;TABLE&gt;

&lt;CAPTION&gt;

<S>	<C>
Revenues:	
Product sales to related party and others	\$
Other income	
Interest income	
	-----
Total Revenues	-----
Costs and Expenses:	
Cost of product sales to related party and others	
Research and development	
General and administrative	
Interest expense-net	
	-----
Total Costs and Expenses	-----
Net loss	\$ (
	=====
Net loss per common share - basic and diluted	
	=====
Weighted average number of common shares	
outstanding - basic and diluted	30,45
	=====

&lt;/TABLE&gt;

The accompanying notes are an integral part of the consolidated financial statements.

4

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## ORGANOGENESIS INC.

Consolidated Statements of Cash Flows  
(Unaudited, in thousands)

&lt;TABLE&gt;

&lt;CAPTION&gt;

<S>	<C>
Cash flows from operating activities:	
Net loss	
Adjustments to reconcile net loss to cash flows used in operating activities:	
Depreciation	
Amortization of warrants and deferred debt issuance costs relating to long-term convertible debt	

## Changes in assets and liabilities:

- Inventory
- Other current assets and receivable from related party
- Other assets
- Accounts payable
- Accrued expenses and other current liabilities
- Advance from related party

Cash provided by (used in) operating activities

## Cash flows from investing activities:

- Capital expenditures
- Sales and maturities of investments

Cash provided by investing activities

## Cash flows from financing activities:

- Proceeds from issuance of long-term convertible debt
- Receivable from debt financing
- Term loan
- Preferred stock redeemed in cash
- Proceeds from sale of common stock - net
- Proceeds from exercise of stock options

Cash provided by financing activities

Increase (decrease) in cash and cash equivalents

Cash and cash equivalents, beginning of period

Cash and cash equivalents, end of period

## Supplemental Disclosure of Cash Flow Information:

- Interest paid in cash during the period

</TABLE>

The accompanying notes are an integral part of the consolidated financial statements.

5

<PAGE>

ORGANOGENESIS INC.

Notes to Consolidated Financial Statements  
(Unaudited)

1. Basis of Presentation

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The accompanying unaudited consolidated financial statements of Organogenesis Inc. have been prepared in accordance with generally accepted

accounting principles for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by generally accepted accounting principles for complete financial statements. In the opinion of management, the accompanying consolidated financial statements include all adjustments, consisting of normal recurring adjustments, necessary for a fair presentation of the financial position, results of operations and changes in cash flows for the periods presented. The results of operations for the three months ended March 31, 2000 are not necessarily indicative of the results to be expected for the year ending December 31, 2000.

These financial statements should be read in conjunction with the audited consolidated financial statements and notes thereto included in our Form 10-K for the year ended December 31, 1999 as filed with the Securities and Exchange Commission.

Certain reclassifications have been made to the prior period financial statements to conform to the current presentation.

## 2. Revenue Recognition

-----

Research and development support revenue under a collaborative agreement with Novartis Pharma AG ("Novartis") is recognized as related expenses are incurred or contractual obligations are met and is not refundable. Revenue from Apligraf sales is recognized upon shipment or, in certain cases, after fulfillment of firm purchase orders in accordance with the Manufacturing and Supply Agreement with Novartis and when risk of ownership passes to the buyer and we have no performance obligations. Other product revenues are recognized upon shipment. Royalty revenue is recorded as earned. Grant revenue is recognized to the extent of allowable costs incurred. Deferred revenue arises from the difference between cash received and revenue recognized in accordance with these policies.

SEC Staff Accounting Bulletin No. 101, "Revenue Recognition in Financial Statements" (SAB 101), was issued in December 1999 and summarizes certain of the Staff's views in applying generally accepted accounting principles to revenue recognition in financial statements. The application of the guidance in SAB 101 will be required by the second quarter of 2000. The effects of applying this guidance, if any, will be reported as a cumulative effect adjustment resulting from a change in accounting principle. Our evaluation of SAB 101 is not yet complete.

## 3. Net Loss Per Common Share

-----

Net loss per common share (basic and diluted) is based on the weighted average number of common shares outstanding during each period. Potentially dilutive securities at March 31, 2000 include: stock options outstanding to purchase 5,222,810 common shares; warrants to purchase 900,000 common shares; and debt convertible into 1,957,384 common shares; however, such securities have not been included in the net loss per common share calculation because their effect would be antidilutive.

6

<PAGE>

## 4. Inventory

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Inventory is stated at the lower of cost or market, cost being standard cost, which approximates the first-in, first-out method of accounting. Inventory, at net realizable value, consisted of the following (in thousands):

	December 31, 1999	March 31, 2000
	-----	-----
		(unaudited)
Raw Materials	\$ 348	\$ 355
Work in Process	558	617
	-----	-----
	\$ 906	\$ 972
	=====	=====

#### 5. Receivable and Advance from Related Party

-----

Receivable from related party consisted of amounts due on product sales to Novartis and funding of certain programs by Novartis. Advance from Novartis of \$5,000,000 was received in advance of achievement of a milestone related to the diabetic foot ulcer indication. If achievement of the milestone is not met, some or all of this payment may be refundable to Novartis.

#### 6. Accrued Expenses

-----

Accrued expenses consisted of the following (in thousands):

	December 31, 1999	March 31, 2000
	-----	-----
		(unaudited)
Compensation and employee benefits	\$1,402	\$1,416
Accrued taxes on stock option exercises	-	3,941
Professional services	825	268
Accrued interest	361	750
Other	850	1,225
	-----	-----
	\$3,438	\$7,600
	=====	=====

7

<PAGE>

#### 7. Term Loan Agreement

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In November of 1999, we entered into a \$5,000,000 term loan agreement with a commercial bank to finance the purchase of certain equipment, leasehold improvements and other items. Borrowings under the term loan are collateralized by a security interest in the items financed. The agreement provides repayment of the principal amount of the loan in 12 equal quarterly installments commencing December 29, 2000, with final payment due on September 30, 2003. The loan bears interest at a fluctuating rate per annum that is equal to the prime rate in effect from time to time, or we may elect that all or any portion of any term loan be made as a LIBOR loan with an interest period of one month, two months, three months or six months with the interest rate being equal to LIBOR plus an applicable margin (175 to 225 basis points). We are required to comply

with certain covenants relating to our outstanding term loans, involving limitations on future indebtedness, dividends and investments, and to maintain certain financial covenants pertaining to liquidity, capital base, and debt service coverage (or, alternatively, maintaining a minimum unencumbered cash balance). We are in compliance with these covenants at March 31, 2000. At March 31, 2000, we had borrowed \$4,728,000 against this term loan to finance certain research, manufacturing and office equipment and leasehold improvements. The weighted average interest rate paid during this period was 8.43%. The current portion of this term loan is \$788,000 at March 31, 2000 and is included in other current liabilities.

#### 8. Series C Redeemable Convertible Preferred Stock

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At December 31, 1999, we had 62 shares of Series C redeemable convertible preferred stock outstanding. In March 2000, we redeemed for cash all outstanding shares of Series C redeemable convertible preferred stock for \$6,180,000.

#### 9. Commitments

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##### Construction-in-Progress

At March 31, 2000, we had approximately \$5,047,000 in construction in progress relating to expansion of our main facility. Additionally, we have committed approximately \$700,000 for further build-out.

##### Grants

In November 1999, we received notice of grants to support two research projects: (1) \$2,000,000 grant under the Advanced Technology Program of the National Institute for Standards and Technology ("NIST") to help support development of an effective liver assist device prototype, which we have received \$51,000 and expect to receive the remaining amount over the period through December 2001; and (2) \$100,000 grant under the Small Business Innovation Research Program of the National Institutes of Health to support development of a vascular graft, which was fully received as of March 31, 2000. Both of these grants require that the United States federal government can access for its own purposes technology developed using the funding. A product developed based on the funding from the NIST grant must be manufactured substantially in the United States. In addition, we are subject to regular audit and reporting requirements. We have recorded revenue of \$184,000 for the three months ended March 31, 2000 relating to these research grants.

8

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#### 10. Common Stock Issuance

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On February 14, 2000, the Securities and Exchange Commission declared effective a shelf registration for the placement of up to 3,000,000 shares of common stock with an aggregate offering price not to exceed \$50,000,000. In February 2000, we completed a private placement of 788,925 shares of common stock at \$14.00 per share under this shelf registration yielding net proceeds of approximately \$10,755,000. In March 2000, we completed a private placement of 300,000 shares of common stock at \$17.25 per share under this shelf registration yielding proceeds of approximately \$5,175,000.

During the three months ended March 31, 2000, we issued 2,295,885 shares of common stock for the exercise of employee stock options, yielding proceeds of

approximately \$10,127,000.

11. Accounting Pronouncements

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In March 2000, the Financial Accounting Standard Board issued FASB Interpretation No. 44, "Accounting for Certain Transactions Involving Stock Compensation - an interpretation of APB Opinion No. 25" ("FIN 44"). FIN 44 clarifies the application of APB Opinion No. 25 and among other issues clarifies the following: the definition of an employee for purposes of applying APB Opinion No. 25; the criteria for determining whether a plan qualifies as a noncompensatory plan; the accounting consequence of various modifications to the terms of previously fixed stock options or awards; and the accounting for an exchange of stock compensation awards in a business combination. FIN 44 is effective July 1, 2000, but certain conclusions in FIN 44 cover specific events that occurred after either December 15, 1998 or January 12, 2000. The Company does not expect the application of FIN 44 to have a material impact on the Company's financial position or results of operations.

9

<PAGE>

ORGANOGENESIS INC.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

This Form 10-Q contains forward-looking statements that involve risks and uncertainties. Forward-looking statements include information on:

- . Our business outlook and future financial performance;
- . Anticipated profitability, revenues, expenses and capital expenditures;
- . Future funding and expectations as to any future events; and
- . Other statements that are not historical fact and are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 that involve risks and uncertainties.

Although we believe that our plans, intentions and expectations reflected in or suggested by such forward-looking statements are reasonable, we can give no assurance that such plans, intentions or expectations will be achieved. When considering such forward-looking statements, you should keep in mind the risk factors and other cautionary statements in this Form 10-Q and in other publicly available filings with the SEC, such as our Annual Report on Form 10-K for the year ended December 31, 1999. The risk and other factors noted throughout this Form 10-Q could cause our actual results to differ materially from the results contained in any forward-looking statements.

In Management's Discussion and Analysis ("MD&A"), we explain the general financial condition and results of operations for Organogenesis Inc. As you read this MD&A, referring to our consolidated financial statements contained in Item 1 of this Form 10-Q may be helpful. Results of operations may vary significantly from quarter to quarter depending on, among other factors, the progress of our research and development efforts, the receipt of milestone and research and development support payments, if any, from Novartis, product revenues, manufacturing costs, the timing of certain expenses and the establishment of additional collaborative agreements, if any.

Overview of Organogenesis Inc.

Organogenesis Inc. - a tissue engineering firm - designs, develops and manufactures medical products containing living cells and/or natural connective tissue. We are the developer and manufacturer of the only mass-manufactured medical product containing living human cells marketed in the United States. Our product development program includes living tissue replacements, cell-based organ assist devices and other tissue-engineered products. Our lead product, Apligraf(R) skin construct, was launched in the United States in June 1998 by Novartis Pharma AG ("Novartis"). Our strategy is to commercialize products either by ourselves or through partners with an established marketing presence.

#### Our Lead Product, Apligraf(r)

-----

Apligraf is approved and marketed in the United States for the treatment of venous leg ulcers. In December 1999, Organogenesis applied to the FDA for marketing approval for a second indication - diabetic foot ulcers. On May 8, 2000, the General and Plastic Surgery Devices Advisory Panel to the FDA recommended approval of Apligraf for diabetic foot ulcers. The FDA takes this recommendation into consideration when developing its final decision. Novartis has global Apligraf marketing rights. In the fourth quarter of 1999, Novartis began initial product introduction in Switzerland, the first of several planned in Europe. Novartis also markets Apligraf in Canada.

Apligraf(R) is a registered trademark of Novartis.

10

<PAGE>

A pivotal trial is underway designed to assess whether use of Apligraf to treat wounds due to skin cancer surgery leads to a better cosmetic outcome. Data from smaller Apligraf studies, including in donor site wounds, burns and epidermolysis bullosa (a genetic skin disorder), have been published or presented.

#### Our Pipeline

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Our pipeline includes Vitrix soft tissue replacement product, now in pilot human clinical trials; our vascular graft program, currently in animal studies; and our liver assist device program, currently in research. Our portfolio also includes potential licensing opportunities. These opportunities include: GraftPatch(TM) soft tissue reinforcement product, which has been cleared for marketing through the FDA 510k process; TestSkin(TM) II, an in vitro testing product; our conditioned medium, a cell culture product found to stimulate the generation of certain skin cell types.

#### Results of Operations

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With the approval and launch of Apligraf, we began a new era of operations. We are seeing, as expected, a gradual ramp-up in sales. We expect production costs to exceed product sales for the near term due to start-up expenses and the high costs associated with low volume production. However, we expect production volume to increase.

#### Revenues

Total revenues were \$1,084,000 for the three months ended March 31, 2000, compared to \$679,000 for the same period in 1999. Product sales to related party and others increased to \$646,000 for the three months ended March 31,

2000, compared to \$318,000 for the same period in 1999, due to increased unit sales of Apligraf to Novartis. We expect Apligraf commercial sales to continue to increase. Other income increased to \$251,000 for the three months ended March 31, 2000, compared to \$168,000 for the same period in 1999, mainly due to funding received under research grants, offset by a decrease in Novartis funding of certain programs.

#### Costs and Expenses

**Cost of product sales:** Cost of product sales was \$1,191,000 for the three months ended March 31, 2000, compared to \$603,000 for the same period in 1999, due to increased unit sales of Apligraf to Novartis. Cost of product sales includes the direct costs to manufacture and package Apligraf and an allocation of our production related indirect costs. Cost of product sales exceeded product sales due to the start-up costs of new product introduction and the high costs associated with low volume production. We expect production volume to increase and our margins to improve. We expect to continue to expand production operations during 2000.

**Research and development:** Research and development expenses ("R&D") consist of costs associated with research, development, clinical and operations support. These expenses decreased to \$4,318,000 for the three months ended March 31, 2000, compared to \$4,488,000 for the same period in 1999. The decrease was due to: approximately \$172,000 net decrease in R&D related expenses primarily due to decreased costs to support sponsored research programs and publications studies; approximately \$238,000 net decrease in clinical related costs due to higher expenses in 1999 relating to the Apligraf diabetic ulcer pivotal trial; offset by an approximate \$240,000 net increase in quality systems and operations support related to increased unit sales of Apligraf. Quality systems and operations support was \$2,028,000 for the three months ended March 31, 2000, compared to \$1,788,000 for the same period in 1999. We expect to continue to advance the product pipeline during 2000.

11

<PAGE>

**General and administrative expenses:** General and administrative expenses ("G&A") include the costs of our corporate, finance, information technology and human resource functions. G&A expenses increased to \$1,782,000 for the three months ended March 31, 2000, compared to \$1,514,000 for the same period in 1999. The increase is primarily due to higher occupancy costs, outside services and consulting fees. We expect the growth in G&A expenses to increase at a slower rate during 2000 than in 1999.

**Interest expense-net:** Interest expense net of \$96,000 capitalized interest, was \$479,000 for the three months ended March 31, 2000 due to the issuance of convertible debentures in March 1999 and entering into a term loan in November 1999.

#### Net Loss

As a result of the net effect described above, we incurred a net loss of \$6,686,000 or \$.21 per share (basic and diluted), for the three months ended March 31, 2000, an increase from the net loss of \$5,926,000, or \$.19 per share (basic and diluted), for the comparable 1999 period.

#### Capital Resources and Liquidity

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#### Funds Used in Operations



At March 31, 2000, we had cash, cash equivalents and investments in the aggregate amount of \$32,323,000 and working capital of \$21,194,000, compared to \$12,439,000 and \$2,981,000, respectively, at December 31, 1999. Cash equivalents consist of money market funds, which are highly liquid and have original maturities of less than three months. Investments consist of securities that have an A or A1 rating or better with a maximum maturity of two years. Net cash provided by operating activities was \$1,721,000 for the three months ended March 31, 2000, primarily due to cash received from Novartis in advance of achievement of a milestone related to the diabetic foot ulcer indication and cash received for taxes on stock option exercises, offset by financing of our ongoing research, development and manufacturing. Cash used in operating activities was \$6,035,000 for the three months ended March 31, 1999, primarily due to the net loss from financing of ongoing research, development and manufacturing operations.

#### Capital Spending

Capital expenditures were \$1,320,000 and \$1,493,000 during the three months ended March 31, 2000 and 1999, respectively, primarily related to the further build-out of existing facilities to support Apligraf manufacturing, as well as the acquisition of equipment for research and development programs and manufacturing. We will continue to utilize funds during 2000 to expand our existing facility in the areas of Apligraf manufacturing, quality systems labs, and packaging.

#### Novartis Support

The collaborative agreement with Novartis provides us with up to \$40,000,000 in equity investments and nonrefundable research, development and milestone support payments, of which \$26,750,000 was received prior to 1999, all of which are non refundable. The remaining payments are based upon achievement of specified events. In March 2000, we received \$5,000,000 from Novartis, which represents a support payment received in advance of achievement of a milestone related to the diabetic foot ulcer indication. If achievement of the milestone is not met, some or all of this payment may be refundable to Novartis. Under the agreement, we supply Novartis' global requirements for Apligraf and receive revenue consisting of a per unit manufacturing payment and royalties on product sales.

12

<PAGE>

#### Financing

From inception, we have financed our operations substantially through private and public placements of equity securities, as well as receipt of research support and contract revenues, interest income from investments, sale of products and receipt of royalties. During the first quarter of 2000, financing activities provided additional cash and working capital of approximately \$19,483,000 from the sale of common stock that generated net proceeds of \$15,930,000 and the exercise of stock options of \$10,127,000, partially offset by the redemption of Series C redeemable convertible preferred stock in cash for \$6,180,000 and term loan for 394,000. Financing activities provided cash for the first quarter of 1999 from the sale of five-year convertible debentures and warrants to purchase common stock that generated gross proceeds of \$20,000,000 and the exercise of stock options of \$130,000.

In November 1999, we received notice of grants to support two research projects: (1) \$2,000,000 grant under the Advanced Technology Program of the

National Institute for Standards and Technology ("NIST") to help support development of an effective liver assist device prototype, which we have received \$51,000 and expect to receive the remaining amount over the period through December 2001; and (2) \$100,000 grant under the Small Business Innovation Research Program of the National Institutes of Health to support development of a vascular graft, which was fully received as of March 31, 2000. Both of these grants require that the United States federal government can access for its own purposes technology developed using the funding. A product developed based on the funding from the NIST grant must be manufactured substantially in the United States. In addition, we are subject to regular audit and reporting requirements. We have recorded revenue of \$184,000 for the three months ended March 31, 2000 relating to these research grants.

#### Liquidity

Based upon current plans, we believe that proceeds received from common stock issued in the first quarter, together with existing working capital and future funds from Novartis, including product and royalty revenue, will be sufficient to finance operations into 2001. However, this statement is forward-looking and changes may occur that would significantly decrease available cash before such time. Factors that may change our cash requirements include:

- . Delays in obtaining regulatory approvals of products in different countries, if needed, and subsequent timing of product launches;
- . Delays in commercial acceptance and reimbursement when product launches occur;
- . Changes in the progress of research and development programs; and
- . Changes in the resources devoted to outside research collaborations or projects, self-funded projects, proprietary manufacturing methods and advanced technologies.

Any of these events could adversely impact our capital resources, requiring us to raise additional funds. Management believes that additional funds may be available through equity or debt financing, strategic alliances with corporate partners, capital lease arrangements, or other sources of financing in the future. There can be no assurances that these funds will be available when required on terms acceptable to us, if at all. If adequate funds are not available when needed, we would need to delay, scale back or eliminate certain research and development programs or license to third parties certain products or technologies that we would otherwise undertake ourselves, resulting in a potential material adverse effect on our financial condition and results of operations.

13

<PAGE>

#### Additional Cautionary Considerations

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We are subject to risks common to entities in the biotechnology industry, including, but not limited to, the following uncertainties:

- . Market acceptance of our products, if and when approved, and successful marketing and selling of Apligraf by Novartis;
- . FDA approval of Apligraf for other indications and successful registrations of Apligraf outside the United States;
- . Risk of failure of clinical trials for future indications of Apligraf and other products;
- . Compliance with FDA regulations and similar foreign regulatory bodies;
- . Manufacture and sale of products in sufficient volume to realize a

satisfactory margin;

- . Continued availability of raw material for products;
- . Availability of sufficient product liability insurance;
- . Ability to recover the investment in property and equipment;
- . Protection of proprietary technology through patents;
- . Development by competitors of new technologies or products that are more effective than ours;
- . Adequate third-party reimbursement for products;
- . Dependence on and retention of key personnel; and
- . Availability of additional capital on acceptable terms, if at all.

14

<PAGE>

ORGANOGENESIS INC.

## Part II - Other Information

### Item 2. Changes in Securities

In March 2000, a former officer of the company exercised an option granted in 1987 to purchase 732,423 shares of common stock at an aggregate purchase price of \$2,250,000. This option was issued under an exemption in section 4(2) of the Securities Act of 1933 as amended. A registration statement covering these shares was declared effective by the SEC on May 8, 2000.

### Item 6. Exhibits and Reports on Form 8-K

#### (a) Exhibits

- |        |  |
|--------|--|
| 10(dd) | Addendum to The License and Supply Agreement between the Company and Novartis Pharma AG, dated March 15, 2000. |
| 27     | Financial Data Schedule (filed with electronic submission only)  |

(b) No current reports on Form 8-K were filed during the quarter ended March 31, 2000.

15

<PAGE>

ORGANOGENESIS INC.

#### Signatures

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Organogenesis Inc.  
(Registrant)



Date: May 15, 2000  
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/S/ Philip M. Laughlin  
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Philip M. Laughlin, President  
and Chief Executive Officer  
(Principal Executive Officer)

Date: May 15, 2000  
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/S/ John J. Arcari  
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John J. Arcari, Vice President Finance, and  
Administration, Chief Financial Officer,  
Treasurer and Secretary  
(Principal Financial and Accounting Officer)

16

<PAGE>

ORGANOGENESIS INC.

# EXHIBIT INDEX

Exhibit No.	Description of Exhibit
10(dd)	Addendum to The License and Supply Agreement between the Company and Novartis Pharma AG, dated March 15, 2000.
27	Financial Data Schedule (filed with electronic submission only)

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<TYPE>EX-10

<SEQUENCE>2

<DESCRIPTION>ADDENDUM TO THE LICENSE AND SUPPLY AGREEMENT

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Exhibit 10(dd)

## ADDENDUM DATED MARCH 15, 2000 TO THE LICENSE AND SUPPLY AGREEMENT DATED JANUARY 17, 1996

Between

Organogenesis, Inc., a company organized under the laws of the State of Delaware, of 150 Dan Road, Canton, MA 02021, USA (hereinafter "Organogenesis")

and

Novartis Pharma AG, a corporation organized under the laws of Switzerland, of Lichstrasse 35, 4056 Basel Switzerland (hereinafter "Novartis")

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WHEREAS, Organogenesis and Novartis entered into a License and Supply Agreement as of January 17, 1996, (the "Agreement")

WHEREAS, The milestones related to subsequent FDA approvals for the Product were modified in an amendment signed January 22/February 4, 1998 between the two companies and the milestone payment for the diabetic ulcer indication was set at

\$5 million; and

WHEREAS, Organogenesis has delivered to Novartis a complete set of the locked and validated clinical data concerning the use of Apligraf (Graftskin) on diabetic foot ulcers and;

NOW, THEREFORE, in consideration of the mutual promises and agreements contained herein and for other good and valuable consideration, the sufficiency and receipt of which are hereto hereby agree as follows:

1. Novartis agrees to pay Organogenesis on or before March 31, 2000 the \$5 million payment related to the diabetic foot ulcer indication set fourth in the Agreement as amended, subject to receipt of an invoice.
2. Organogenesis agrees that the \$5 million payment fulfills Novartis' obligation for the DFU milestone payment set forth in the Agreement, as amended.
3. If the DFU PMA supplement filed December 23, 1999 (the "Supplement") is not approved by March 31, 2001, Novartis may withhold all sums due to Organogenesis under either the Agreement, as amended or under the Global Manufacturing and Supply Agreement dated as of August 11, 1997 by and between Organogenesis and Novartis Pharma AG (the "Supply Agreement") up to five hundred thousand (\$500,000) per month until a total of five million dollars (\$5,000,000) is reached. When the supplement is approved, any money withheld will be paid to Organogenesis.

Furthermore, Novartis shall also be entitled not to take any stock purchases that it may be otherwise obligated to make under the Stock Purchase Agreement dated January 17, 1996, as it may be amended, between Organogenesis and Novartis until a total of 5 million US\$ is recovered by Novartis as described above.

4. Organogenesis, except as required by law, will not disclose any terms of the Addendum without prior written approval of Novartis.
5. Capitalized terms used herein that are not defined herein, shall have the meaning ascribed to them in the Agreement, as amended.

All of the other terms and condition of the Agreement shall remain in full force and effect.

IN WITNESS WHEREOF, the parties hereto have executed this addendum Agreement as of the date first hereunder,

NOVARTIS PHARMA AG

ORGANOGENESIS INC.

-----  
Dr. J. Reinhardt  
Head Clinical Development  
and Project Management

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James S. New  
Head of Global Business  
Development & Licensing  
Date: March 15, 2000

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Philip Laughlin  
President, CEO

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THIS SCHEDULE CONTAINS SUMMARY FINANCIAL INFORMATION EXTRACTED FROM FORM 10-Q  
 AND IS QUALIFIED IN ITS ENTIRETY BY REFERENCE TO SUCH FINANCIAL STATEMENTS.

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-----END PRIVACY-ENHANCED MESSAGE-----